DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 12-8-04
Publication Date 12-9-04
Certifier R. VEDESMA

DAM

Food and Drug Administration

[Docket No. 2004D–0327]

Draft Compliance Guidance for Small Business Entities on Labeling Over-the-Counter Human Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance guidance for small business entities entitled "Labeling OTC Human Drug Products; Small Entity Compliance Guide." FDA has prepared this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses better understand the new over-the-counter (OTC) labeling requirements and to prepare new labeling within the prescribed implementation compliance dates.

DATES: Submit written or electronic comments on the draft compliance guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft compliance guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft compliance guidance to the Division of Dockets Management (HFA–305), Food

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and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft compliance guidance document.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin or Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft compliance guidance for small business entities entitled "Labeling OTC Human Drug Products; Small Entity Compliance Guide." FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format regulations for the labeling of OTC drug products. This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulation for this new standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. The new format will require revision of all existing labeling and covers all

OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or product not yet the subject of a final OTC drug monograph). To reduce the economic impact on small business entities, the new regulations provide an additional 1-year period to comply with § 201.66 (21 CFR 201.66) for OTC drug products with sales of less than $25,000 per year. You can find a copy of § 201.66 at the Division of Dockets Management Web site at *http://www.fda.gov/cder/otc/label/label-fr-reg.htm.*

Following issuance of the final rule, the agency received a number of inquires from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the new standardized content and format requirements. This draft guidance summarizes the new Drug Facts labeling requirements as set forth in § 201.66. The draft guidance also describes how to list those inactive ingredients that are different when a finished OTC drug product is obtained from multiple suppliers.

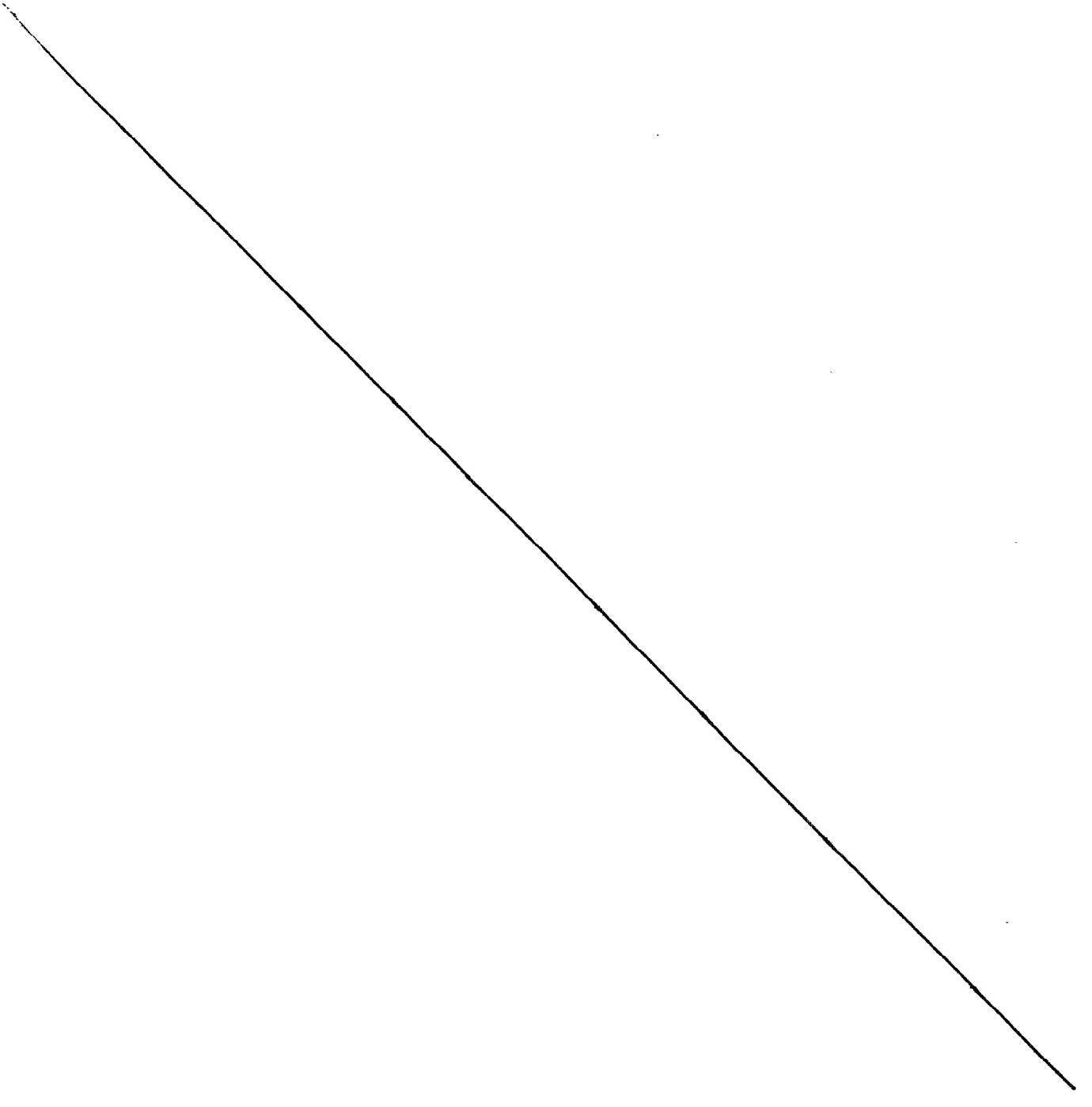
This draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft compliance guidance, when finalized, will represent the agency's current thinking on how OTC drug monograph labeling finalized prior to or after the new requirements can be converted to the new OTC "Drug Facts" format labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft compliance guidance.

JJ per Kent Bill OFR 12-6-04

Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft compliance guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 12/1/04
December 1, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S